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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,724	10/22/2003	Scott H. Gillis	14072-036001 / W 617	7679
26161 7590 03/20/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/20/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary  
for Applications  
Under Accelerated Examination**

Application No.

10/690,724

Applicant(s)

GILLIS ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Since this application has been granted special status under the accelerated examination program,  
NO extensions of time under 37 CFR 1.136(a) will be permitted and a SHORTENED STATUTORY PERIOD FOR  
REPLY IS SET TO EXPIRE:

ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,  
FROM THE MAILING DATE OF THIS COMMUNICATION -- if this is a non-final action or a Quayle action.  
(Examiner: For FINAL actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.  
2) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 3) ☒ Claim(s) 1 and 43-47 is/are pending in the application.  
3a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
4) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
5) ☒ Claim(s) 1 and 43-47 is/are rejected.  
6) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
7) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 8) ☐ The specification is objected to by the Examiner.  
9) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
10) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 11) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
• See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/31/07  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

Claims 1 and 43-47 are pending in this application.

It is noted for the record that during a telephone conversation on 3/8/2007 between the Examiner and applicant's attorney, Mr. Daley, an agreement was reached to amend claim 1 to (i) recite an effective amount of the nanocrystalline material, and (ii) limit the nanocrystalline material as being in a suppository or enema. Cancellation of claims 44-47 and amending "comprises" to "is" in claim 43 was also agreed to. However, subsequently, the Examiner found obviousness double patenting issues, which militated against allowance of the claims at this time. On 3/12/2007, Mr. Daley requested an Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 46-47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed nanocrystalline material in a suppository or enema form, does not reasonably provide enablement for other forms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims – see the full discussion in the previous Office action of 10/4/2006, pages 3-7.

This ground of rejection is based on the fact that the scope of the claims is broader than contacting an area of the subject having inflammatory bowel disease with nanocrystalline material that is not in a suppository or enema form. For the reasons of record, other modes of contacting with other forms of the composition would require undue experimentation to use as claimed.

Applicant's arguments relative hereto, filed on 1/31/2007, have been given due consideration but they were deemed unpersuasive to the extent that the claims read on contacting an area of the subject having inflammatory bowel disease with nanocrystalline material that is not in a suppository or enema form. Such broader scope, which encompasses indirect modes of contacting such as swallowing a tablet or solution in particular, lacks adequate enablement for the full reasons set forth in said previous Office action. Examples of formulations are not the same thing as examples of actual therapeutic efficacy.

For these reasons, this ground of rejection must be maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 43, 45 and 47 (to the extent claim 47 reads on enema formulation form) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90-95, 102-112 of copending Application No. 11/434,958. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims are directed to the same subject matter, albeit in claim language that recites broader subject matter. However, treatment of IBD with nanocrystalline material in a suppository form is clearly set forth in the copending claims. Enema is suggested from the liquid forms and contacting claim language. See above noted claims. For these reasons, the invention of the instant claims would have been recognized as an obvious variation of the invention set forth in the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 43-45 and 47 (to the extent claim 47 reads on enema formulation form) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11-22, 27-28, 30-33, 37, 47-57, 61-63, 65-68 of copending Application No. 10/985,204. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims are directed to similar subject matter, albeit in claim language that recites broader subject matter. However, treatment of IBD with nanocrystalline material is clearly set forth in the copending claims. Suppository and enema forms would have been fairly suggested from the various claim-recited formulation forms and contacting claim language. See above noted claims. For these reasons, the invention of the instant claims would have been recognized as an obvious variation of the invention set forth in the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 43, 45 and 47 (to the extent claim 47 reads on enema formulation form) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13-15, 17-19, 21, 27, 32, 72-75, 78-79, 81, 119 of copending Application No. 10/277,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims are directed to similar subject matter, albeit in claim language that recites broader subject matter. However, treatment of IBD with nanocrystalline material is clearly set forth in the copending claims. Enema form would have been fairly suggested from the various claim-recited formulation forms and contacting claim language. See above noted claims. For these reasons, the invention of the instant claims would have been recognized as an obvious variation of the invention set forth in the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

For these reasons, no claim can be allowed at this time. It is noted for the record that an obviousness type double patenting ground of rejection, which contradicts the lack of enablement ground of rejection set forth earlier in this Office action, has not been made.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**.

The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak  
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